

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Hospital Central Fill, Patient Notification, Pharmacist Licensure, Pharmacy Technician Licensure, Fees, Common Electronic Files, and the Authenticity of Prescriptions

Sections Affected: 1710, 1711, 1717.1, 1717.4, 1720, 1721, 1723.1, 1724, 1749, 1793, 1793.1, 1793.2, 1793.4, 1793.5, 1793.6, and 1793.7

Specific Purpose of the Proposed Changes:

Proposed amendments to Section 1710 are designed to permit the filling of patient specific drug cassettes in a pharmacy located outside of the hospital in a manner analogous to that used by community pharmacies pursuant to Title 16, Section 1707.4 of the California Code of Regulations.

Proposed amendments to Section 1711 are designed to clarify when pharmacists must notify patients and prescribers of medication errors.

Proposed amendments to Section 1717.1 require pharmacies employing a common electronic prescription file to prevent unauthorized disclosure of confidential medical information and requires such pharmacies to develop written policies and procedures to ensure the confidentiality of private medical information.

Proposed amendment to Section 1717.4 requires pharmacists to ensure the integrity of a prescription.

Proposed amendments to Section 1720 requires applicants to submit their fee for licensure as a pharmacist within one year of passing the examination. The proposed amendments also require applicants to comply with requirements established by the administrators of the pharmacist licensure examination. Lastly, the time period allowed to take the examination is shortened to one year in conformity with the new examination requirements and shortens the time allowed to pay the fee for licensure to streamline board operations.

Proposed amendments to Section 1721 increases the penalty for dishonest conduct during examinations by prohibiting the applicant from retaking the examination for one year. The amendments also prohibit the issuance of a pharmacy technician license until the applicant is eligible to take the examination again.

Proposed amendments to Section 1723.1 eliminates references to the exemptee examination which is no longer required for licensure as an exemptee.

Proposed amendments to Section 1724 change the standard of passage for the pharmacist licensure examination.

Proposed amendments to Section 1749 are designed to eliminate obsolete fee provisions and to incorporate the fees for pharmacy technicians into this section.

Proposed amendments to Section 1793 eliminate obsolete language.

Proposed amendments to Section 1793.1 Section eliminate obsolete language and delete language that is incorporated elsewhere in a modest reorganization of pharmacy technician provisions.

Proposed amendments to Section 1793.2 eliminates language that is duplicative of language in existing statute.

Proposed repeal of Section 1793.4 eliminates provisions that are inconsistent with the qualifications for licensure as a pharmacy technician by Senate Bill 361 (Chapter 539, Statutes of 2003).

Proposed amendments to Section 1793.5 are designed to conform pharmacy technician application requirements to changes imposed by Senate Bill 361 (Chapter 539, Statutes of 2003) and to eliminate language that duplicates existing statutory provisions.

Proposed amendments to Section 1793.6 delete a requirement that training hours for pharmacy technicians be evenly split between theoretical and practical training.

Proposed amendments to Section 1793.7 eliminates language that that duplicates existing statutory provisions and to incorporate language deleted in other sections by this proposal as a modest reorganization of pharmacy technician provisions.

Factual Basis/Rationale

Section 1710

This proposal will increase the time hospital pharmacists can allocate to providing clinical and drug therapy management services by reducing the time that hospital pharmacists devote to dispensing activities. The proposal will also provide small, rural hospitals that do not have a full-time pharmacy service to increase patient safety and drug therapy management by subjecting medication orders to review by a pharmacist.

Section 1711

Existing regulations could be interpreted to require the redundant notification of patients and prescribers when a medication error occurs. The same regulations could also be interpreted to require patient notification of in a manner that inappropriately disrupts patient care. The proposed amendments preserve the patient notification requirement while providing practitioners with the flexibility to make that notification in the most appropriate and effective manner.

Section 1717.1

The proposed changes clearly establish a pharmacy's obligation to protect the confidentiality of patient medical information in common electronic prescription files. Such files provide patients with greater flexibility in the locations at which they can have their prescriptions filled but, absent adequate policies and procedures, could subject confidential patient information to unauthorized disclosure. The proposed language requires pharmacies to take affirmative steps to preserve patient privacy.

Section 1717.4

The proposed changes are designed to reduce the filling of fraudulent prescriptions. The question of a prescription's authenticity has been highlighted by the advent of electronic prescription systems, but the question of a prescription's authenticity is valid for all the different forms that a prescription may take. The proposed amendment would make the authenticity of a prescription and personal and professional obligation, thereby increasing the integrity of the prescribing process.

Section 1720

The proposed changes are designed to conform existing board processes to the examination changes established by Senate Bill 361 (Chapter 539, Statutes of 2003). The new examination is offered continuously thereby eliminating the need for application cut-off dates. The proposed amendments also shorten the period of time to take the examination after applying and the time allowed to pay the licensure fee after qualifying for a pharmacist license to streamline board operations.

Section 1721

The proposed changes increase the penalties for dishonest conduct related to the pharmacist licensure examination. The new examination will be offered continuously on a nationwide basis which will provide more opportunities for violations of exam security which will be balanced by the more severe penalties.

Section 1723.1

The proposed changes eliminate reference to the exemptee examination because the board no longer requires an exemptee applicant to pass an examination to receive a license.

Section 1724

The proposed changes are designed to reflect the methodology for establishing passing grades used by the pharmacist licensure examination in accordance with accepted testing standards.

Section 1749

The proposed changes eliminate obsolete fees and incorporate fees for licensure as a pharmacy technician. Previously, the fee for pharmacy interns was included in Section 1793.5.

Section 1793

The proposed changes are technical in nature and intended to make the section easier to read.

Section 1793.1

The proposed changes are technical in nature and reflect a modest reorganization of provisions related to pharmacy technicians.

Section 1793.2

The proposed changes eliminate language that duplicates provisions in existing statute.

Section 1793.4

This section is repealed because Senate Bill 361 (Chapter 539, Statutes of 2003) establishes the requirements for licensure as a pharmacy technician.

Section 1793.5

The proposed changes are designed to conform existing board processes to changes related to pharmacy technicians established by Senate Bill 361 (Chapter 539, Statutes of 2003).

Section 1793.6

The proposed changes are designed to provide greater flexibility to the design of pharmacy technician training programs. This flexibility will allow training programs to be composed of theoretical and practical training in proportions that best prepare pharmacy technician trainees. The change will also streamline the processing of pharmacy technician applications received from graduates of technician training programs.

Section 1793.7

The proposed changes are technical in nature and reflect a modest reorganization of provisions related to pharmacy technicians.

Underlying Data

None.

Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the absence of testimony indicating adverse economic impact regarding these rulemaking proposals at the informational hearings held by the board.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.